



K092004

P. 1 of 3

AUG 25 2009

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: 1 st July 2009

Submitter: GE Healthcare [GE Medical Systems, LLC]
Doing business with GE Healthcare
3000 N. Grandview Blvd
Waukesha, WI 53188

Primary Contact Person: Alan Totah
Regulatory Affairs Director, Pre-market
GE Healthcare
(262) -544-3424
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Secondary Contact Person: Philip Malca
Interventional Regulatory Affairs Director
GE Healthcare GE Medical Systems SCS.
33 1 30 70 42 07
33 1 30 70 43 99

Device: Trade Name: Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz

Common/Usual Name: Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz

Classification Names: System X-Ray, Angiographic

Product Code: DWB, JAA, 121

Predicate Device(s): Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ}
K052412, K050489, K060259, K061163
IC-PRO device (K083745) featuring StentOp
Philips Fresco release 1 (featuring StentBoost) (K031836)

Device Description: The Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} Systems are modified with an optional software feature called StentViz. The StentViz feature enhances the visibility of stents in the x-ray images produced by the Innova systems. Specifically, StentViz provides an enhanced static image of the stent that is derived from the video image sequence as recorded during fluoroscopic guidance. It does not provide real-time guidance.

Intended Use: The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier technology. These devices are not intended for mammography applications.



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Technology: The Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: The subject device is of a comparable type and substantially equivalent to the unmodified Innova 4100^{IQ}, Innova 3100^{IQ}, Innova 2100^{IQ} devices. For the purpose of comparison, the modified and unmodified devices are identical except for the additional software option (StentViz). When StentViz is used, the image quality and visibility of the stent is improved. This improvement does not adversely impact safety or effectiveness.

Two other predicate devices contain an equivalent feature to the StentViz:

- Paieon StentOp feature of the IC-PRO device (K083745)
- and Philips Fresco (also known as StentBoost) (K031836).

StentOp is a stand-alone software application that can be used on any fluoroscopy system while StentBoost is a feature embedded in the Philips Fresco fluoroscopy system. Both the StentOp and StentBoost offer the ability to provide an enhanced static image of the stent that is derived from the video image sequence as recorded during fluoroscopic guidance. As these predicate devices, StentViz does not provide real-time guidance. The image quality of the stent is enhanced in a comparable way with StentViz than with StentOp and StentBoost. From a design validation performance standpoint, bench tests were performed based on a library of clinical images. This library was used to assess the enhancement of stent visibility and to compare the performance of the Innova with StentViz to:

- Innova without StentViz applied on the video image sequence as recorded
- the performance of the similar feature contained in the predicate device StentOp. The image quality of the stent is enhanced in a comparable way with StentOp.

The Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz and its applications comply with voluntary standards as detailed in Sections 9 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)



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- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical studies:

The subject of this premarket submission, Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz to be as safe and as effective as the predicate devices, and its performance is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Alan Totah
Director, RA, PreMarket
GE Healthcare Systems
3000 N. Grandview Blvd.
WAUKESHA WI 53188

JUL 30 2012

Re: K092004

Trade/Device Name: Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: July 1, 2009
Received: July 2, 2009

Dear Mr. Totah:

This letter corrects our substantially equivalent letter of August 25, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

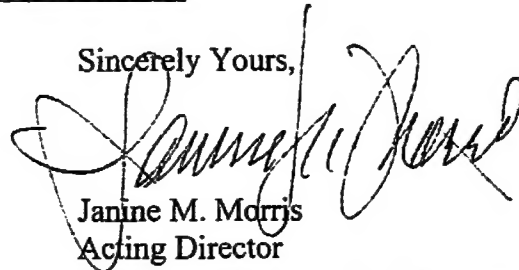
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure



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510(k) Number (if known): K092004

Device Name: Innova 4100^{IQ}, 3100^{IQ}, 2100^{IQ} with StentViz

Indications for Use:

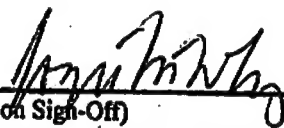
The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier technology. These devices are not intended for mammography applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092004